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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,849	05/22/2001	Sudhir Paul	UNMC 63123DIV	9441

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EXAMINER	
PATTERSON, CHARLES L JR	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/862,849	PAUL ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on th cov r she t with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,8,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,8,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-5, 7 and 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Applicants request that the references cited in 09/046,373 appear on the face of any patent which issues from "the above identified application. It is presumed that "the above identified application refers to this application, 09/862,849, as the references appear on the face of the patent issued on 5/22/01 for 6,235,714, corresponding to 09/046,373. In order for references to appear on the face of any patent issuing from this application a PTO-1449 must be sent. If the references have already been sent they do not have to be sent again.

Draft Figure 1 is approved. A formal drawings must now be submitted. The original Fig. 1 had a ΔG_{rs} and a ΔG_t in the drawings submitted to the patent office. Apparently there was a problem with copying the figures.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite in the recitation of "covalently reactive antigen analog". This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that the term is defined in the specification at page 16, lines 14-20. This section defines CRAAs as "antigen analogs...[that] con-

tain an electrophilic center flanked by peptide residues derived from proteins associated with a particular peptide antigen to be targeted for cleavage and the intended use of the CRAA". This definition does not take into account the usual and accepted meaning of the word "covalent". The term is usually associated with a covalent bond, which is a chemical bond formed by the sharing of one or more electrons. As a part of the instant term has a meaning that does not appear on the surface to correspond to the term, absent a convincing argument to the contrary the term should be defined in the claim. If applicants disagree they should point out how the intended meaning of the term takes into account the usual and accepted meaning of "covalent".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 8 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that the specification discloses on pages 29-40 a method of immunizing mice with a CRAA of an EGFR peptide, screening for

catalytic antibodies produced, assessing their catalytic properties, etc. They further argue that on pages 121-123 it discloses methods of passive immunization with the catalytic antibodies and methods of active immunization with the CRAAs. All of these recitations are in the future tense (e.g. we will do, etc.) and there are absolutely no results shown for the claimed invention anywhere in the specification. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546, 547 and used in determining proper scope in numerous later decisions such as *In re Wands*, 8 USPQ2d 1400, 1404. These factors are (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in that art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. In the present case, (1) the quantity of experimentation is maintained to be extensive since there is only general guidance given (2) and there are absolutely no working example (3). Although the relative skill of those in the art is presumed to be high (6), which particular CRAA will produce catalytic antibodies and which will not is very unpredictable (7). Therefore the claims are too broad (8) as they claiming something that applicants have not done.

Applicant submit a reference, Paul, et al. (W), that shows that when the entire gp120 is altered at all of the Lys residues with hapten "R_3", there were obtained 7 monoclonal antibodies and 3 of these antibodies were catalytic antibodies, specifically cleaving biotinylated gp120. The instant specification teaches using (1) "the phosphonate transition state analog (TSA) of a B cell epitope of gp120 (residues 421-436) conjugated to a T-helper epitope from tetanus toxoid (residues 830-844) [designated B-T epitope]"; (2) "the

phosphonate ester CRAA of the B-T epitope" and (3) "the unmodified peptide form of the B-T epitope" (page 82, lines 5-14). Since the specification does not teach the CRAA that was used to make catalytic antibodies in Paul, et al. (W), it has no probative value in the determination whether the instant specification is enabling or contains a written description of the invention. The instant specification does not teach one of ordinary skill in the art to perform (make) the claimed method and furthermore this ordinary artisan, upon reading the instant specification, would not believe that applicants had possession of the invention when the application was filed.

As to claims 12 and 13, applicants have not shown in the instant specification that either a passive or active immunization has been accomplished. It is maintained that there is an inventive contribution in producing such immunization and, absent a showing that this has been accomplished, applicants have not taught one or ordinary skill in the art how to accomplish these claimed methods.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner, et al. (U). This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that the instant reference does not teach the use of CRAAs to produce catalytic antibodies. As stated previously and as discussed in the 35 USC § 112 second paragraph rejection *supra*, the meaning of CRAAs in not defined in the claims and appears to go against the usual meaning of "covalent". If applicants successfully argue against the 35 USC § 112 second paragraph rejection *supra*, then this rejection would probably be dropped.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
November 26, 2003